Proposed Registration Decision PRD2014-18

Paecilomyces fumosoroseus strain FE 9901

(publié aussi en français)

24 September 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2014-18E (print version)
H113-9/2014-18E-PDF (PDF version)

Table of Contents

Overview

Proposed Registration Decision for *Paecilomyces fumosoroseus* strain FE 9901

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of NoFly Technical and NoFly WP, containing the microbial pest control agent *Paecilomyces fumosoroseus* strain FE 9901, for the control of whiteflies and thrips in greenhouse ornamentals.

NoFly Technical (Registration Number 30090) and NoFly WP (Registration Number 30091) are conditionally registered in Canada. The detailed review for NoFly Technical and NoFly WP can be found in Evaluation Report ERC2011-07, *Paecilomyces fumosoroseus* strain FE 9901. The current applications were submitted to convert NoFly Technical and NoFly WP from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of NoFly Technical and NoFly WP.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of the Health Canada website at healthcanada.gc.ca/pmra.

Before making a final registration decision on *P. fumosoroseus* strain FE 9901, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on *P. fumosoroseus* strain FE 9901, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is *Paecilomyces fumosoroseus* strain FE 9901?

P. fumosoroseus strain FE 9901 is a microbial pest control agent used to control whiteflies and thrips in greenhouse ornamentals. *P. fumosoroseus* strain FE 9901 is an entomopathogen that infects and kills insects. The end-use product, NoFly WP, is a commercial insecticide that contains *P. fumosoroseus* strain FE 9901 as the active ingredient.

Health Considerations

Can Approved Uses of *Paecilomyces fumosoroseus* strain FE 9901 Affect Human Health?

***P. fumosoroseus* strain FE 9901 is unlikely to affect your health when NoFly WP is used according to the label directions.**

People could be exposed to *P. fumosoroseus* strain FE 9901 when handling and applying NoFly WP. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

---

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When spores of *P. fumosoroseus* strain FE 9901 were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease. Furthermore, *P. fumosoroseus* strain FE 9901 does not grow at temperatures above 35°C and no adverse effects to *P. fumosoroseus* were reported in published scientific literature.

Residues in Water and Food

Dietary risks from water and food are not of concern.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

As there are no direct applications to food, there is no concern for risks posed by dietary exposure of the general population, including infants and children, or animals. Consequently, the establishment of an MRL is not required for *P. fumosoroseus* strain FE 9901. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Occupational Risks From Handling NoFly WP

Occupational risks are not of concern when NoFly WP is used according to label directions, which include protective measures.

Growers handling NoFly WP can come into direct contact with *P. fumosoroseus* strain FE 9901 on the skin, in the eyes or by inhalation. For this reason, the product label specifies that growers exposed to this end-use product must wear waterproof gloves, long-sleeved shirts, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), long pants and shoes plus socks. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When NoFly WP Is Introduced Into the Environment?

Environmental risks are not of concern.

Following application, *P. fumosoroseus* strain FE 9901 is likely able to survive in the environment under favourable environmental conditions (in other words, temperature, humidity), but over time, populations of *P. fumosoroseus* strain FE 9901 are expected to return to natural background levels.

The effects of *P. fumosoroseus* strain FE 9901 on beneficial and/or environmentally-important insects were examined. Studies showed that *P. fumosoroseus* strain FE 9901 was toxic or infectious to some beneficial insects, however, no adverse effects to wasps were found. The end-use product label will advise users that NoFly WP may be harmful to pollinators, including bees, and to some beneficial insects, and will alert users to avoid applying NoFly WP directly to bees while they are foraging. This is a precautionary measure aimed at minimizing exposure of bees even though there are no reports indicating that *P. fumosoroseus* is pathogenic or toxic to bee species.

Although avian pulmonary/inhalation/injection, wild mammal, fish, aquatic insect, earthworms, microorganisms, and plant testing were not conducted, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected. There are no published reports of disease associated with P. fumosoroseus strain FE 9901 in birds, wild mammals, fish, aquatic insects, earthworms, microorganisms, and plants. Also, minimal exposure to non-target organisms is anticipated from the use of NoFly WP to control whiteflies and thrips in greenhouses.

Value Considerations

What Is the Value of NoFly WP?

Applied as a foliar spray, NoFly WP controls whiteflies and thrips on greenhouse crops and is compatible with the use of *Encarsia* species as biological control agents.

The value of NoFly WP is that it provides an effective alternative for control of whiteflies and thrips in the greenhouse environment. Whiteflies and thrips are serious pests of a wide variety of greenhouse crops in Canada and certain species have been known to develop resistance to chemical insecticides. NoFly WP provides a non-chemical mode of action and has been shown to be compatible with the use of *Encarsia* species, parasitoids that are commonly used as biological control agents for whiteflies in greenhouses.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of NoFly WP to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As with all microbial pest control products, there are concerns with users developing allergic reactions through repeated high exposures to *P. fumosoroseus* strain FE 9901. Therefore, anyone handling NoFly WP must wear waterproof gloves, long-sleeved shirts, a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products), long pants and shoes plus socks. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential. An additional risk reduction measure is a 4-hour restricted entry interval immediately following product application. All early-entry workers to treated sites will be required to wear personal protective equipment, including a NIOSH-approved respirator until spray mists have settled.

Environment

As a general precaution, the label prohibits the direct application of the product to aquatic habitats (such as lakes, streams and ponds). The label also directs growers to not allow effluent or run-off from greenhouses containing this product to enter lakes, streams, ponds or other waters and to avoid contaminating surface water by disposal of equipment wash waters. The product label further advises users that NoFly WP may be harmful to pollinators (including bees) and to some beneficial insects that may be used in greenhouse integrated pest management programs. A statement will also instruct users to avoid direct applications to bees while they are foraging.

Next Steps

Before making a final registration decision on *P. fumosoroseus* strain FE 9901, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on *P. fumosoroseus* strain FE 9901 (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Paecilomyces fumosoroseus strain FE 9901

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Please refer to Evaluation Report ERC2011-07, *Paecilomyces fumosoroseus* strain FE 9901.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Please refer to Evaluation Report ERC2011-07.

1.3 Directions for Use

NoFly WP is used for controlling whiteflies and thrips on all greenhouse ornamental crops.

Apply at rates of 2-3 g product per litre of water. Apply sufficient spray volume for thorough coverage of the crop, depending on the size of the plants, up to a maximum of 2000 L/ha at the high rate, and up to a maximum of 3000 L/ha at the low rate. Ensure spray coverage includes the undersides of the leaves. Begin applications at the first sign of pest presence. Reapply at 15-day intervals, or shorter (5-8 days) in the case of heavy infestations, until the pest is gone. Applications should be conducted during low solar radiation (late afternoon or evening) when there is high relative humidity inside the greenhouse and the temperature is below 30°C.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Please refer to Evaluation Report ERC2011-07.

2.2 Method for Formulation Analysis

Please refer to Evaluation Report ERC2011-07.

2.3 Methods for Residue Analysis

Potency data on a sufficient number of batches of technical grade active ingredient were found to be acceptable. Confirmatory potency estimation data on five batches of end-use product produced at the proposed manufacturing site will be required as a condition of full registration.

2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites

Please refer to Evaluation Report ERC2011-07.

2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

The quality control procedures used to limit contaminating microorganisms during manufacture of NoFly Technical and NoFly WP are acceptable.

The absence of human pathogens and below-threshold levels of contaminants was demonstrated in representative batches of technical grade active ingredient using established detection methods. Microbe-specific screening methods for yeasts/moulds, *Escherichia* coli, *Salmonella* spp., *Shigella* spp., *Vibrio* spp., *Listeria monocytogenes* and *Psuedomonas aeruginosa* are adequate for detecting and enumerating microbial contaminants of concern. Release standards for microbial contaminants in the production batches comply with those permitted by the PMRA and are adequate to ensure that the end-use product does not contain unacceptable levels of human and animal disease-causing microorganisms.

2.6 Methods to Determine Storage Stability, Shelf-life of the Microorganism

Please refer to Evaluation Report ERC2011-07.

3.0 Impact on Human and Animal Health

Please refer to Evaluation Report ERC2011-07 for an assessment of the impact on human and animal health.

4.0 Impact on the Environment

Please refer to Evaluation Report ERC2011-07 for an assessment of the impact on the environment.

5.0 Value

Refer to Evaluation Report ERC2011-07 for details of the value assessment supporting the initial registration of NoFly WP.

No further value information was required as a condition for the initial registration of NoFly WP. Subsequent to the initial registration, additional value information was provided to support the addition of thrips to the label and to expand the application rate to a range of rates, resulting in the currently supported directions for use (see Section 1.3 for details).

6.0 Pest Control Product Policy Considerations

Please refer to Evaluation Report ERC2011-07 for pest control product policy considerations.

7.0 Summary

7.1 Methods for Analysis of the Micro-organism as Manufactured

The product characterization data for NoFly Technical and NoFly WP were deemed adequate to assess their potential human health and environmental risks. The specifications of the technical grade active ingredient and end-use product were supported by the analyses of a sufficient number of batches.

7.2 Human Health and Safety

The acute toxicity and infectivity studies and other relevant information submitted in support of *P. fumosoroseus* strain FE 9901 were determined to be sufficiently complete to permit a decision on registration. Spores of *P. fumosoroseus* strain FE 9901 were not pathogenic or infective in the rat via the oral and intraperitoneal injection exposure routes and were not pathogenic or infective to the ferret via the pulmonary exposure route. An equivalent end-use product to NoFly WP, Futureco NoFly, was of low toxicity to the rat via the oral, inhalation and dermal exposure routes, and was slightly irritating to the skin and eyes of rabbits. Futureco NoFly was a sensitizer to guinea pigs and was not a mutagen in bacterial assays.

When handled according to prescribed label instructions, the potential for dermal, eye and inhalation exposure for applicators, mixer/loaders, and handlers exists, with the primary source of exposure to workers being dermal and to a lesser extent inhalation. Precautionary statements on the NoFly WP label and the wearing of personal protective equipment by workers will adequately mitigate the risks from exposure. While *P. fumosoroseus* strain FE 9901 is a sensitizing agent, inhalation and dermal exposure is not a concern if the required dust/mist filtering respirator/mask and appropriate personal protective equipment stipulated on the NoFly WP label are worn by handlers and applicators. Furthermore, precautionary labelling will alert users of the potential sensitization hazard of the product.

The health risk to general population, including infants and children, as a result of bystander exposure and/or chronic dietary exposure is expected to be minimal since NoFly WP will only be applied to greenhouse ornamentals. The product is not to be applied to residential or recreational areas or to food or feed crops.

7.3 Environmental Risk

The non-target studies on beneficial arthropods and bees, scientific rationale and supporting published scientific literature submitted in support of *P. fumosoroseus* strain FE 9901 were determined to be sufficiently complete to permit a decision on registration. The use of NoFly WP containing *P. fumosoroseus* strain FE 9901 is not expected to pose a risk to birds, mammals, aquatic arthropods, fish, plants and other microorganisms, but may pose a risk to certain beneficial insects and pollinators present in treated greenhouses as well as to non-target terrestrial arthropods and non-arthropod invertebrates present on treated greenhouse crops. These effects are expected to be limited to the treated areas and their immediate surroundings.

No additional studies were required to address the environmental fate and behaviour of *P. fumosoroseus* strain FE 9901. Environmental fate data are higher tier requirements and are not normally required in the absence of significant toxicological effects in non-target organisms in Tier I testing. Environmental exposure to *P. fumosoroseus* strain FE 9901 is expected to be minimal given that the use of NoFly WP is limited to greenhouses.

As a general precaution, the NoFly WP label prohibits the direct application of NoFly WP to aquatic habitats (such as lakes, streams and ponds) and the release of greenhouse effluent and run-off to natural aquatic systems. The label also directs users to avoid contaminating surface water by disposal of equipment wash waters.

The product label also advises users that NoFly WP may be harmful to pollinators (including bees) and to some beneficial insects that may be used in greenhouse integrated pest management programs. A statement also instructs users to avoid directly exposing bees while they are foraging.

7.4 Value

NoFly WP has value for control of whiteflies and thrips on ornamental crops grown in greenhouses.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of NoFly Technical and NoFly WP, containing the microbial pest control agent *P. fumosoroseus* strain FE 9901, to control whiteflies and thrips in greenhouse crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

DACO	data code
ERC	evaluation report
g	gram
ha	hectare
HE	high efficiency
L	litre
MRL	maximum residue limit
NIOSH	National Institute for Occupational Safety and Health
PMRA	Pest Management Regulatory Agency
ssp.	subspecies
WP	wettable powder

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

2316654 2013. 5 Batch Analysis for Nofly wettable powder (Registration Numbers 30091). DACO M2.10.2, M2.9.2.

2316625 2013. 5 Batch Analysis for Nofly Technical (Registration Numbers 30090). DACO M2.10.2, M2.9.2.